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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,257

Applicant(s)

ITOH, KYOGO

Examiner

DiBrino Marianne

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-123 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-XVI. Claims 1, 3, 7 and 44, drawn to a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, respectively, cancer vaccine comprising said peptide, pharmaceutical composition thereof, classified in Class 530, subclass 328, Class 424, subclass 185.1, respectively.

XVII-XXXII. Claims 9, 11, 13, 15, 17, 19, 21, 23, 46, 48, 50, 52, 54, 56, drawn to a polynucleotide encoding a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, respectively, a hybridizing polynucleotide, a recombinant vector comprising said polynucleotide encoding a peptide, transformed host cell comprising said recombinant vector and method for producing a peptide comprising culturing said transformed host cell, classified in Class 536, subclasses 23.5 Class 435, subclasses 69.1, 252.3, 320.1, 440.

XXXIII-XLIX. Claim 25, drawn to an antibody that immunologically recognizes a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, respectively, classified in Class 530, subclass 387.7.

L-LXVI. Claim 27, drawn to a method for screening a compound that interacts with a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17 and enhances the recognition property by at least one of HLA-A2402-restricted CTL or HLA-A2-restricted CTL, said method comprising contacting said peptide with said compound, classified in Class 435, subclass 7.1.

LXVII-LXXXIII. Claims 29, 31, 33 and 35, drawn to a method for screening a compound that interacts with a polynucleotide encoding a polypeptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, or with a vector comprising said polynucleotide, classified in Class 435, subclasses 91.1 and 320.1.

LXXXIV-C. Claims 37 and 39, drawn to a method for screening a compound that interacts with a transformed host cell, classified in Class 435, subclass 252.3.

CI-CXVII. Claim 41, drawn to a method for screening a compound that interacts with a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, and enhances the recognition property by at least one of HLA-A2402-restricted CTL or HLA-A2-restricted CTL, said method comprising contacting a transformant with a compound, classified in Class 435, subclass 252.3.

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CXVIII-CXXXIV. Claim 43, drawn to a compound that interacts with a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, and enhances the recognition property by at least one of HLA-A2402-restricted CTL or HLA-A2-restricted CTL, classified in Class 530, subclass 328.

CXXXV-CLI. Claims 5, 58, 60, 62, 76, 77, 80, 81, 84 and 85, drawn to a method for inducing CTL or for treating cancer, said method comprising administering to a patient a peptide inducer of CTL, said peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, classified in Class 424, subclass 185.1 and Class 514, subclass 15.

CLII-CLXVIII. Claims 64, 66, 68, 70, 88, 89, 92, 93, 96, 97, 100 and 101, drawn to a method for treating cancer, said method comprising administering a pharmaceutical composition comprising a polynucleotide encoding a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, a hybridizing polynucleotide thereof or a recombinant vector comprising said polynucleotide encoding a peptide, classified in Class 514, subclass 44

CLXIX-CLXXXV. Claims 72, 74, 104, 105, 108 and 109, drawn to a method for treating cancer, said method comprising administering a pharmaceutical composition comprising a transformant cell comprising a polynucleotide encoding a peptide having an amino acid sequence of ONE of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 or 17, classified in Class 424, subclass 93.1.

2. Claims 2, 4, 6, 8, 45 and 117 link Inventions I, II, IV, V, VI, VII, VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 2, 4, 8, 45 and 117. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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3. Claims 10, 12, 14, 16, 18, 20, 22, 24, 47, 49, 51, 53, 55, 57, 118, 119 and 120 link Inventions XVII, XVIII and XX-XXV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 10, 12, 14, 16, 18, 20, 22, 24, 47, 49, 51, 53, 55, 57, 118, 119 and 120. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claims 26 and 121 link Inventions XXXIII, XXXIV and XXXVI-XLI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 26 and 121. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Claim 28 links Inventions L, LI and LIII-LVIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claim 28. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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6. Claims 30, 32, 34, 36, 38, 40 and 42 link Inventions LXVII, LXVIII, LXX-LXXV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 30, 32, 34, 36, 38, 40 and 42. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Claims 59, 61, 63, 78, 79, 82, 83, 86 and 87 link Inventions CXXXV, CXXXVI and CXXXVIII-CXLIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 59, 61, 63, 78, 79, 82, 83, 86 and 87. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Claims 65, 67, 69, 71, 73, 75, 90, 91, 94, 95, 98, 99, 102, 103, 106, 107, 110 and 111 link Inventions CLII, CLIII and CLV-CLX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 65, 67, 69, 71, 73, 75, 90, 91, 94, 95, 98, 99, 102, 103, 106, 107, 110 and 111. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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9. Claim 122 links Inventions LXVII-LXXXIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 122. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

10. Claim 123 links Inventions XVII, XVIII and XX-XXIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 123. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

11. Claim 112 links Inventions L-LXVI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 112. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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12. Claims 113 and 114 link Inventions LXVII-LXXXIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claims 113 and 114. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

13. Claim 115 links Inventions LXVII-LXXXIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 115. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

14. Claim 116 links Inventions CI-CXVII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 116. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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15. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Inventions I-XVI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of any two (or more of) the claimed SEQ ID NO does not necessarily rely solely on either subcombination for patentability as evidenced by both subcombinations being within the same combination. The subcombination has separate utility such as for inducing a CTL response.

17. Inventions XVII-XXXII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of any two (or more of) the claimed SEQ ID NO does not necessarily rely solely on either subcombination for patentability as evidenced by both subcombinations being within the

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same combination. The subcombination has separate utility such as for inducing a CTL response or producing a peptide or screening for an enhancer of CTL activation.

18. Inventions XXXIII-XLIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct antibodies that are not disclosed as capable of use together since they have different sequences and each ligand to which each antibody is specific for is not obvious over the other set of ligands.

19. Inventions of Groups I-XVI, XVII-XXXII, XXXIII-XLIX and CXVIII-CXXXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the Inventions of Groups I-XVI are peptides which are comprised of amino acid residues that bind to a particular MHC class I molecule, the Inventions of Groups XVI-XXXII are polynucleotides, vectors and host cells thereof that are comprised of nucleotides and encode the said peptides, the Inventions of Groups XXIII-XLIX are proteins that are antibodies that react with the said peptides nominally, i.e., not in context with MHC class I molecules, and the Inventions of Groups CXVII-CXXXIV are compounds that interact with a peptide that binds to a particular MHC class I molecule, the said compounds not necessarily peptides or proteins, that enhance the recognition property by at least one MHC class-I restricted CTL.

20. Inventions of Groups XVII-XXXII, L-LXVI, LXVII-LXXXIII, LXXXIV-C, CI-CXVII, CXXXV-CLII, CLII-CLVIII and CLXIX-CLXXXV are different methods.

These inventions require different ingredients and process steps to accomplish the use of: producing a peptide by culturing a transformed host cell (XVII-XXXII), screening a compound that interacts with a peptide and enhances a recognition property by a CTL (L-LXVI), screening a compound that interacts with a polynucleotide or vector thereof that encodes a peptide (LXVII-LXXXIII), screening a compound that interacts with a transformed host cell comprising a nucleic acid encoding a peptide, not necessarily interacting with the peptide encoded by the said transformed host cell (LXXXIV-C), screening a compound that interacts with a peptide by contacting a transformant with a compound (CI-CXVII), inducing CTL or treating cancer by administering a peptide(s) (CXXXV-CLII) or by administering a pharmaceutical composition comprising a polynucleotide/vector thereof/complementary or hybridizing polynucleotide thereof, encoding a peptide (CLII-CLVIII), or treating cancer by administering a pharmaceutical composition comprising a transformed cell (CLXIX-CLXXXV).

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21. Inventions of Groups I-XVI and the Inventions of Groups L-LXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or as an immunogen.

22. Inventions of Groups XVII-XXXII and the Inventions of Groups LXVII-LXXXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or as an immunogen.

23. Inventions of Groups XVII-XXXII and the Inventions of Groups LXXXIV-C are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or as an immunogen or for making a protein.

24. Inventions of Groups XVII-XXXII and the Inventions of Groups CI-CXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or as an immunogen or for making a protein.

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25. Inventions of Groups I-XVI and the Inventions of Groups CXXXV-CL are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or in detection assays.

26. Inventions of Groups XVII-XXXII and the Inventions of Groups CLII-CLXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or in detection assays.

27. Inventions of Groups XVII-XXXII and the Inventions of Groups CLXIX-CLXXXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in detection assays.

28. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-CLXXXV is not required for any other group from Groups I-CLXXXV and Groups I-CLXXXV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

29. **If Applicant elects one of the Inventions of Groups I-XVI**, Applicant is further required to (1) elect a single disclosed species (**a specific peptide having an amino acid sequence, inducer of CTL and vaccine thereof**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus, an inducer of CTL comprising the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus, and vaccine comprising the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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These species are distinct because their structures are different.

30. **If Applicant elects one of the Inventions of Groups XVII-XXXII**, Applicant is further required to (1) elect a single disclosed species (**a polynucleotide/vector thereof and host cell thereof encoding a specific peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

31. **If Applicant elects one of the Inventions of Groups XXXIII-XLIX**, Applicant is further required to (1) elect a single disclosed species (**a specific antibody that specifically recognizes a peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

32. **If Applicant elects one of the Inventions of Groups L-LXVI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a specific peptide having an amino acid sequence and a specific compound**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus **and** a single disclosed species of compound **and** a specific single disclosed recognition property) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added. These species are distinct because their structures are different.

33. **If Applicant elects one of the Inventions of Groups LXVII-LXXXIII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a polynucleotide/vector thereof and host cell thereof encoding a specific peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus **and** a single disclosed species of compound **and** a specific method step to determine enhancement of expression) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

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34. **If Applicant elects one of the Inventions of Groups LXXXIV-C**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a host cell transformed with a specific polynucleotide/vector encoding a specific peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus **and** a single disclosed species of compound **and** a specific method step to determine enhancement of expression) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

35. **If Applicant elects one of the Inventions of Groups CI-CXVII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a host cell transformed with a specific polynucleotide/vector encoding a specific peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus **and** a single disclosed species of compound **and** a specific single disclosed recognition property) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

36. **If Applicant elects one of the Inventions of Groups CXVIII-CXXXIV**, Applicant is further required to (1) elect a single disclosed species of compound that interacts with a specific species of peptide (a single disclosed species of compound that interacts with **a specific peptide having an amino acid sequence**, for example, a compound that interacts with a peptide consisting of the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

37. **If Applicant elects one of the Inventions of Groups CXXX-CLI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method **and** whether the treatment is *in vivo* or *in vitro* (**a specific peptide/inducer/vaccine thereof having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus, an inducer of CTL comprising the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus, and vaccine comprising the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus and *in vitro*) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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38. **If Applicant elects one of the Inventions of Groups CLII-CLXVIII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method **and** whether the treatment is *in vivo* or *in vitro* (**a composition comprising a polynucleotide encoding a specific peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus and *in vitro*) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

39. **If Applicant elects one of the Inventions of Groups CLXIX-CLXXXV**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method **and** whether the treatment is *in vivo* or *in vitro* (**a composition comprising a cell transformed with a polynucleotide/vector thereof encoding a specific peptide having an amino acid sequence**, for example, the entire sequence of SEQ ID NO: 1 flanked by ED at the carboxy terminus and *in vitro*) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

40. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

41. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

42. Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

43. Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

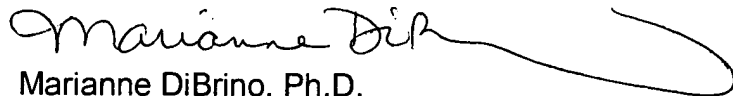
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44. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.


45. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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